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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2012-0049]

Ongoing Equivalence Verifications of Foreign Food Regulatory Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is describing the new methodology it is employing to conduct ongoing equivalence verifications of the regulatory systems of countries that export meat, poultry, or processed egg products to the United States. FSIS uses a three-part approach that includes: (1) document reviews, (2) on-site system audits, and (3) port-of-entry (POE) reinspections. FSIS conducts document reviews at least yearly. FSIS conducts on-site system audits at least once every three years. FSIS determines the scope and frequency of on-site systems audits and POE reinspections through analysis of the results of its document reviews and an assessment of a country's performance. This performance-based approach allows FSIS to direct its resources to foreign food regulatory systems that pose greater risk to public health compared to others; make its international program more consistent with its domestic inspection system; and improve the

linkage between POE reinspections and on-site audits. As a result, FSIS is able to effectively prevent unsafe imports from entering this country.

DATE: Comments on this notice should be received by [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0049. Comments received in response to this docket will be made available for public inspection and posted without change,

including any personal information, to

<http://www.regulations.gov>.

DOCKET: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mary Stanley, Director, International Policy Division, Office of Policy and Program Development, FSIS, USDA, South Agriculture Building, Room 2925, 1400 Independence Avenue SW, Washington D.C. 20250; Telephone: (202) 720-0287, Fax: (202) 720-4929 or Email: mary.stanley@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 620) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 466) prohibit the importation of meat and poultry products into the United States if such products are adulterated or misbranded, and unless they comply with all the inspection and other provisions of the Acts and regulations that are applied to U.S. domestic products. The Egg Products Inspection Act (EPIA) (21 U.S.C. 1046) prohibits the importation of egg products unless they have been processed under an approved continuous inspection system of the government of the foreign country of origin and

comply with all other provisions of the Act and regulations that apply to U.S. domestic products.

The USDA has had a comprehensive program to assess foreign meat and poultry establishments since 1967. Initially, the Department inspected certified foreign establishments to determine whether they were "at least equal to" comparable U.S. establishments. Department officials were stationed in Washington, D.C., Argentina, Costa Rica, Australia, New Zealand, Denmark, Germany, Belgium, and Canada. This program continued until 1988, when it was substantially revised, and all overseas auditors were recalled to Washington, D.C. On-site establishment inspections continued under the revised program based upon past on-site audit findings and POE reinspection results.

In 1994, the concept of equivalence was introduced in the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations signed in Marrakech. The SPS Agreement became effective in January 1995, concurrently with establishment of the World Trade Organization (WTO), which superseded the General Agreement on Tariffs and Trade (GATT) as the umbrella organization for international trade. Because the U.S. is a signatory to the SPS Agreement and a member of the WTO, FSIS amended its regulations to require

foreign meat and poultry food regulatory systems to be "equivalent to" comparable U.S. requirements (60 FR 38667; July 28, 1995).

In the late-1990's, FSIS shifted the emphasis of its on-site audits from inspecting establishments to assessing a country's food regulatory system. This change was announced in the Federal Register on December 17, 1999 (64 FR 70690; December 17, 1999). Under this approach, the scope of on-site audits was broadened to include country laws and documents related to program implementation; records of establishment operations, inspection results, and enforcement activities; chemical residue controls from farm to slaughter; microbiological and chemical testing programs; laboratory support, sampling programs, and sampling and testing methodologies; and other U.S. import requirements such as pathogen reduction and HACCP programs.

Statutory requirements for equivalence are set forth in 9 CFR 327.2 for meat products, 9 CFR 381.196 for poultry products, and 9 CFR 590.910 for egg products. FSIS has categorized these requirements into six "equivalence components." Specifically, FSIS evaluates a country's national government to ensure that it is imposing equivalent requirements with respect to: (1) government oversight, (2) statutory authority and food safety regulations, (3) sanitation, (4) hazard analysis and critical control points (HACCP), (5) chemical residues, and (6)

microbiological testing programs. This comprehensive process is described fully on the FSIS web site at

<http://www.fsis.usda.gov/pdf/eqprocess.pdf>.

Any country can apply for eligibility to export meat, poultry, or egg products to the U.S. Based on its review of the information and documentation that the country submits, FSIS decides whether the foreign country's food regulatory system meets all U.S. import requirements in the same or an equivalent manner and cumulatively provides the same level of public health protection as that attained domestically. If so, FSIS plans an on-site audit of the entire foreign meat, poultry, or egg products regulatory system. When both the document analysis and on-site audit review show that the country meets U.S. requirements, FSIS publishes a proposed rule in the Federal Register that announces the results of the first two steps and proposes to add the country to its list of eligible exporting countries in the regulations. After analysis of public comments, FSIS makes a final decision about whether the country's system is equivalent based upon all available information and publishes a final rule in the Federal Register announcing its determination on country eligibility.

Once a foreign country's inspection system is deemed equivalent,¹ FSIS continues to evaluate the country's inspection system to ensure equivalence is maintained. FSIS performs this activity through a three-part process, involving: (1) document reviews, (2) on-site system audits, and (3) POE reinspections.

In 2008, FSIS held a public meeting with the National Advisory Committee on Meat and Poultry Inspection (NACMPI) to review and discuss international equivalence and the approach to verifying the equivalence of foreign food regulatory systems as the means of ensuring the safety of imported food products (73 FR 48190; August 18, 2008). FSIS requested NACMPI's guidance on: (1) Whether elements of the "triad of protection" (i.e., document reviews, on-site audits, and POE reinspections) should be changed; (2) Whether regulatory information and compliance history from foreign countries should affect audits and re-inspections; and (3) Whether the scope and frequency of on-site audits and POE re-inspections should be adjusted based on the capability of a country to share useful regulatory information and compliance history.

¹ FSIS regulations list 46 countries as eligible to export meat, nine countries as eligible to export poultry, and two countries as eligible to export egg products to the United States (see 9 CFR 327.2(b), 381.196(b), and 590.910(b)). However, some of these countries have outstanding issues that will require additional document submission and review, as well as on-site equivalence verification prior to resuming exports. In 2012, only 29 countries actively exported meat, poultry, and egg products to the United States. FSIS maintains a list of eligible countries, along with their status and whether they are approved to export meat, poultry, and egg products to the United States:
http://www.fsis.usda.gov/pdf/Countries_Products_Eligible_for_Export.pdf.

After reviewing all comments and materials presented at the meeting, NACMPI recommended that FSIS maintain its three-part approach to equivalence but direct Agency resources according to the relative risks and historical compliance presented by each foreign food regulatory system. NACMPI stated that considering the foreign food regulatory system's past performance provides a more objective and efficient method of allocating FSIS resources to address food safety risks and public health concerns than conducting annual on-site audits. NACMPI also recommended that FSIS standardize its methods for the collection of information from foreign governments, collaborate with the Codex Alimentarius Commission (CODEX) concerning the Codex Committee on Food Import and Export Inspection and Certification Systems' new work on guidance for on-site audits,² and incorporate specific elements into its ongoing verification activities. These specific elements included the use of the three-tiered approach based on risk. With respect to audits, NACMPI recommended the standardized application of on-site audit criteria and an historical evaluation of the trading country's on-site audit outcomes. As for document reviews, it recommended an assessment of the exporting country's on-going ability and willingness to share data, as well as the quality of data shared. Finally, with respect to POE re-inspections, NACMPI

² Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification (CAC/GL 26-1997).

recommended the targeting of high-risk product and high-risk imports for sampling and other verification activities during reinspection. NACMPI also recommended that FSIS maintain open communication with all involved in the import process.

New Approach

In 2009, in response to NACMPI's recommendations, FSIS modified its three-part method for verifying the equivalence of foreign food regulatory systems by developing a performance-based approach for determining the scope and frequency of its on-site systems audits and POE reinspections. Thus, FSIS transitioned from an annual on-site audit to less frequent on-site audits based on performance. FSIS makes information about all on-site audits available to the public on its Web site.

It took FSIS some time to work through the mechanics of this transition. Fully training its auditors and other aspects of the transition occurred over a period of years rather than on a fixed date. Preparation of this notice to announce this transition also took longer than contemplated. Now that the transition is fully in place, FSIS is announcing it to the public.

Document Reviews

As part of the transition, FSIS developed the Self-Reporting Tool (SRT), which structures the criteria used to assess each component of initial and on-going equivalence

through a series of questions. FSIS uses the SRT to collect information for the Agency's document review of a foreign country's food safety system. FSIS conducts these document reviews at least annually. Along with responses to the questions in the SRT, FSIS asks exporting countries to submit their inspection system laws, regulations, and policy issuances to support their answers. FSIS asks countries to update this information as changes in U.S. domestic policy warrant the need for additional information from foreign governments to demonstrate that an equivalent inspection system is being maintained, or as changes are made in the foreign country's system. Also through the SRT, FSIS requests that foreign governments report what actions they take when non-compliant products are shipped. The SRT affords countries the opportunity to advise FSIS of any new controls they have implemented since their last submission (e.g., microbial baseline studies, ongoing risk assessments, internal audit programs) to demonstrate the effectiveness of their food safety regulatory systems.

The SRT represents a significant improvement over the collection mechanisms used by FSIS in the past. FSIS previously used the Self-Assessment Tool (SAT), which was limited to initial equivalence requests and not updated on a regular basis. Unlike the SAT, the SRT collects information for both the initial and ongoing equivalence verification processes. Doing

so makes it easier for countries to update their information. In addition, it allows FSIS to standardize its collection of information. This standardization improves the quality of information that FSIS receives and, thus, improves FSIS's ability to evaluate a country's performance.

The SRT permits FSIS to identify key documents on which to evaluate system effectiveness and to assess any impacts that an administrative or legislative change has had on a foreign regulatory system. It also enables FSIS to monitor corrective actions that countries take in response to shipping non-compliant product to the U.S. The current and detailed information that the SRT provides allows FSIS to conduct more comprehensive assessments of foreign countries' food safety regulatory systems while remaining at USDA Headquarters in Washington, D.C. These comprehensive assessments allow FSIS to use its resources more effectively and efficiently, both on and off site, while still ensuring the safety of imported products.

On-Site Systems Audits

Under this new approach, FSIS conducts on-site audits of countries eligible to export product to the U.S. at least once every three years. The new approach provides for at least the same level of public health protection as FSIS's previous approach with annual on-site audits. During an on-site systems audit, an FSIS auditor (or an audit team, when necessary)

verifies that the national government is adequately implementing the country's food safety laws and regulations, and that through its oversight of its inspection personnel, the government is verifying that establishments' process controls (e.g., laboratory testing programs, sanitation standard operating procedures, and HACCP) are effective. When the FSIS auditor determines that controls are not being implemented as designed, and there is significant question as to whether the products produced are safe, unadulterated, and properly labeled and packaged, he or she takes appropriate action.

The frequency and scope of on-site audits are based on the results of FSIS's country performance assessment. The performance assessment focuses on each eligible country's overall food safety performance relative to the performance of other eligible countries. The first step in the assessment is a statistical analysis of compliance data from POE reinspections and previous on-site audits of the country's government offices, establishments, and laboratories. Because a single, composite measure cannot completely characterize a country's performance, FSIS incorporates a number of supplemental, qualitative factors into its assessment.

The supplemental factors are derived from the Codex Alimentarius Commissions' Guidelines on the Judgment of Equivalence of Sanitary Measures associated with Food Inspection

and Certification systems ([CAC/GL 53-2003](#)), and the principles outlined in the joint Food and Agricultural Office of the United Nations (FAO) and World Health Organization (WHO) publication [Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems](#).³ These factors include: the results of audits, inspections, and field examinations conducted by FSIS and third countries; the use of risk analysis principles; the impact of organizational, structural, or administrative change in an exporting country's competent authority; the availability of contingency plans in the country for containing and mitigating the effects of food safety emergencies; the competent authority's willingness and ability to take appropriate actions to manage food safety incidents; and the effectiveness of foodborne disease surveillance systems. For each supplemental factor, FSIS assigns a level of advancement (LOA) to measure the foreign food regulatory system's ability to demonstrate compliance with that supplemental factor. FSIS assigns countries LOA levels 1, 2, or 3, with 3 being the highest level.

For example, one supplemental factor that FSIS evaluates is whether the Agency has knowledge that an exporting country

³ FAO/WHO. 2003. [Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems](#). Food and Nutrition Paper No. 76. Food and Agriculture Organization of the United Nations. Rome, Italy (available at: http://www.who.int/foodsafety/publications/fs_management/guidelines_foodcontrol/en/).

applies risk analysis principles in its food safety system. A country that could not demonstrate that its risk management decisions are generally supported by a scientific risk assessment would receive a level one LOA. A country that could demonstrate that its risk management decisions are generally supported by scientific principles and evidence, including risk assessments, would receive a level two LOA. A country that could demonstrate that it consistently bases its risk management decisions on risk assessments would receive a level three LOA.

FSIS uses the statistical analysis results and the LOA assignments to characterize a country's recent food safety performance as well-performing, average-performing, or adequately-performing (i.e., the country is eligible to export meat, poultry, and egg products to the U.S., but its performance has not reached the same level of confidence as that of its peers).

In general, countries that are performing well receive less frequent, more narrowly defined on-site audits, while "adequately-performing" countries receive more frequent and more comprehensive audits. FSIS selects the specific facilities to be audited (i.e., government offices, establishments, and laboratories) by evaluating the volume of products that are produced, the relative hazards associated with those products, the government's compliance history, and previous POE

reinspection results. When selecting establishments to visit during an on-site systems audit, FSIS directs its resources to establishments with larger production volumes, that produce product associated with a higher level of risk⁴, that produce product identified during previous on-site audits as being non-compliant, or that produce product for which there were positive microbiological or residue POE reinspection results.

As noted above, FSIS schedules on-site systems audits at a minimum frequency of once every three years. Under this approach, adequately performing countries receive audits every year, average-performing countries receive audits every two years, and countries that are performing well receive audits every three years. This frequency is based on NACMPI's recommendation that FSIS adopt a risk-informed approach. It is also based on FSIS's determination, in light of the audits that it has conducted over the years, that annual visits are not necessary to countries whose systems are performing in an average way or well. Visits every two or three years to these countries, given the other information that is available to FSIS, provide the necessary assurance that products of these foreign systems generally will be safe, unadulterated, and

⁴ For example, raw ground beef is considered to be a "riskier" product than raw intact beef because the contaminated meat surface is broken into small fragments and spread throughout the ground product.

properly labeled and packaged. FSIS welcomes comment on this judgment.

In addition to the periodic audits, FSIS conducts more targeted "for cause" audits. The Agency conducts these audits in response to repetitive POE findings of public health significance or other conditions representing a lack of process control within a country's food safety system.

POE Reinspections

FSIS's POE activities monitor the effectiveness of exporting countries' inspection systems and overall food safety programs. All shipments of meat, poultry, and egg products that enter the U.S. must be presented to an FSIS inspector either at one of the approximately 130 official FSIS import facilities located at major ocean ports and land border crossings, or at an alternative location designated by the Agency (see 9 CFR 327.6, 381.199, and 590.925). FSIS reinspects every shipment for eligibility through certification by the national government, acceptable condition of the product, and labeling compliance. In addition, FSIS performs more detailed, random reinspections that include physical examination of product and of hermetically sealed containers, as well as microbiological and chemical testing. If products meet FSIS's standards, they are marked as "Inspected and Passed" and released into U.S. commerce. However, if FSIS identifies non-compliant products, it notifies

both the government of the country that exported the products and the importer, marks the products as "Refused Entry," and prohibits the products from entering U.S. commerce.

In order to focus its resources on the products that may pose the greatest threat to public health, FSIS uses the country performance assessment described above, and other factors such as product type and species, to determine the scope and frequency of the randomly assigned POE activities such as pathogen testing, food chemistry sampling, and species verification. In addition, on May 29, 2012, FSIS launched a comprehensive, Web-based data analytics system called the Public Health Information System (PHIS) as part of its efforts to collect, consolidate, and analyze data. PHIS builds upon the previous Automated Import Inspection System (AIIS) used by FSIS since 1979 through the increased integration of FSIS's existing data streams. PHIS also enables FSIS to collect information from external sources through an electronic interface with Customs and Border Protection's Automated Commercial Environment (ACE), including foreign government electronic certification systems. These enhancements further support a performance-based approach to POE reinspection.

As with AIIS, PHIS automatically schedules a more intensive reinspection (i.e., increased follow-up sampling) of shipments from foreign establishments that produce products failing

reinspection at POE, or products identified as the sole raw material source for ground beef that has tested positive for pathogenic STEC in the U.S. PHIS provides the ability to automatically adjust frequencies for pathogen testing, food chemistry sampling, and species verification based on a particular countries performance classification.

If non-compliant imported shipments are detected, FSIS works with the government of the country that exported the product to ensure that appropriate corrective actions are effected. As indicated previously, the foreign government reports through the SRT what actions it will take when non-compliant products are shipped. That information serves as the basis for FSIS's follow-up verification activities.

If a country makes any modifications to its inspection system, FSIS requires that the country update its responses to FSIS's SRT accordingly (see 9 CFR 327.2(a)(2)(iii), 381.196(a)(2)(iii), and 590.910(a)). Changes to the SRT may affect the results of a country's performance assessment, which then may affect the scope and frequency of subsequent equivalence verification activities. Thus, FSIS's performance-based approach improves the linkage between POE reinspections and on-site audits.

Furthermore, if repeated failures from a particular establishment indicate a loss of process control, and FSIS finds

that the foreign country's corrective actions are not effective, FSIS will take action to suspend the eligibility of the establishment and may conclude that a "for cause" on-site audit is necessary. When multiple establishments in a country repeatedly fail POE reinspections, FSIS will consider elevating its action to a system level that could affect the eligibility of the foreign inspection system.

Additional Public Notification

FSIS will announce this notice on-line through the FSIS Web page located at

http://www.fsis.usda.gov/regulations_and_policies/Federal_Register_Notices/index.asp.

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals and other individuals who have asked to be included. The Update is available on the FSIS

Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/News & Events/Email Subscription/>.

Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Done in Washington, DC, on: January 18, 2013.

Alfred V. Almanza
Administrator.

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